ANACS

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Acting Commissioner
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

November 22, 2004

Dear Commissioner,

The members of the Association of Nurse Advocates for Childbirth Solutions have grave concerns regarding the use of misoprostol for induction of labor at term. We are concerned that this medication has been adopted for use as a matter of convenience to both practitioners and institutions with little regard for reported potential catastrophic outcomes for both mothers and babies.

In general, we believe that there are entirely too many inductions of labor for non-medically valid reasons and that women are unaware of the possible risks of these inductions. Cytotec (misoprostol) is the latest medication to be experimented with for labor induction. The discovery of the fortuitous effects of misoprostol on uterine activity seems to have become enough of a convincer for the obstetric world to warmly embrace it as an efficacious induction agent. Good luck for those that have warmly embraced this means of induction does not negate the reality that many recipients of misoprostol for induction of labor have suffered tetanic uterine activity with devastating outcomes.

We are concerned that there seem to be some women that have unpredictable violent reactions to this medication, that the administration route does not allow for emergent secession of administration, and that women are not being given true informed consent with regard to this medication. We would like to see separate informed consent for misoprostol and access to all information presented on the drug label.

Other agents (Cervidil, Pitocin) allow for quick interruption of treatment via removal of the medication or turning off the intravenous administration. We have spoken with nurses regarding this topic across the country and in our collective experience uterine hyperstimulation caused by misprostil is both unpredictable with regards to onset and response to tocolytic agents.

In an article published in the American Journal of Obstetrics and Gynecology in July 2004 Rozenberg, Chevret, Senat, Bretelle, Paule, and Ville discuss the unpredictability of individual misoprostol response when they admit that "optimal dosage of misoprostol probably varies among individual women" (p. 252). Nurses are concerned that there is no way to predict which patients will have an adverse response to the misoprostol and that it's systemic and cumulative effects are difficult to regulate. Many of us are extremely uncomfortable administering this medication and are concerned about the lack of informed consent surrounding the use of misoprostol.

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We agree with the Cochrane Database reviewer statement "there is no consensus on what constitutes an acceptable risk of labour induction, in the absence of life threatening conditions for mother and baby. It is likely that most parents and clinicians would not be prepared to accept a 0.5% to 1% increase in serious adverse outcome on the grounds of convenience or cost. In fact, it is likely that women would be prepared to spend more time on delivery suite if this means a safer labour"(Alfirevic, 2004). We feel that women need more information to assess the possible risks of induction with misoprostol.

We respectfully request the FDA's action on behalf of the women we serve. We want the public to have adequate information to make informed choices around the medications used in labor. We want the public to know about the reported adverse outcomes from misoprostol use. All labels and information should be readily accessible to the public. We also would encourage the FDA to find solutions for reporting and tracking adverse outcomes with misoprostol and any other medication used in labor.

Sincerely,

Carolyn Rafferty, RN, BSN
Executive Director, Association of Nurse Advocates for Childbirth Solutions

References:

Alfirevic Z. Oral misoprostol for induction of labour. [Software. Research. Systematic Review] *The Cochrane Library, (Oxford) ** (4):2004.*

Rozenberg P. Chevret S. Senat MV. Bretelle F. Paule Bonnal A. Ville Y. A randomized trial that compared intravaginal misoprostol and dinoprostone vaginal insert in pregnancies at high risk of fetal distress. [Clinical Trial. Journal Article. Randomized Controlled Trial] *American Journal of Obstetrics & Gynecology. 191(1):247-53, 2004 Jul.*